

REMARKS

Applicants will address each of the Examiner's rejections in the order in which they appear in the Office Action.

Claim Rejections - 35 USC §102

Claims 19-20

In the Office Action, the Examiner rejects Claims 19-20 under 35 USC 102(b) as being anticipated by Zadini et al. This rejection is respectfully traversed.

Initially, Applicants note that the Examiner has not identified where in the reference the alleged claimed invention is disclosed. Accordingly, the undersigned is forced to speculate as to what the Examiner contends is the claimed invention. It is respectfully submitted that this is an insufficient rejection and does not establish a prima facie case.

Further, Zadini does not disclose or suggest the claimed invention. More specifically, Zadini is directed to a catheter placement device comprising a needle and a needle handle portion 16, not a transfer device as in the claimed invention. Further, it is believed that the Examiner is citing 26 in Zadini as an alleged detent as in the claimed invention. However, independent Claim 19 recites that the detent has a transverse tab for securing said connector in the central opening of the transfer device. This is shown, for example, in Fig. 41C of the present application at reference number 396. See also page 33, lns. 20-33 of the specification.

In contrast, Zadini discloses a hub 20 having a lever 26 which has an opening 28 therein. The needle handle portion 16 has a bridge member 30 with a stud 34. The stud 34 fits into opening 28.

Zadini does not disclose a detent having a transverse tab, as in Claim 19. Further, the reference does not disclose a transverse tab for securing the connector in the center opening of the transfer device, as in Claim 19.

While Applicants believe that this clearly distinguishes the claimed invention from the cited reference, in order to advance the prosecution of this application, Applicants have amended independent Claim 19 to recite “a connector integral with the proximal end of the catheter including at least one detent extending from said connector and having a transverse tab at the end of the detent extending from said connector for securing said connector in the central opening of the transfer device by catching said tab inside said opening of the transfer device, said detent being manually actuable to release the catheter from the central opening of the transfer device by depressing said detent so as to allow said transverse tab to be released from inside said opening of the transfer device.” Thus, in contrast to Claim 19, at the very least, Zadini does not disclose or suggest (1) a detent having a transverse tab at the end of detent, (2) a transverse tab for securing said connector in the central opening of the transfer device, (3) a detent for catching said tab inside said opening of the transfer device, or (4) a detent being manually actuable to release the catheter from the central opening of the transfer device by depressing said detent so as to allow said transverse tab to be released from inside said opening of the transfer device.

Hence, it is respectfully submitted that Claims 19 and 20 are not disclosed or suggested by Zadini and are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

Claims 21, 42-43

The Examiner also rejects Claims 21, 42-43 under 35 USC §103(a) as being unpatentable over Jang et al. in view of Bell or Yock. This rejection is also respectfully traversed.

Claim 21 is directed to a catheter for use in a system for intraluminal treatment of a selected site in a body where the catheter has first and second lumens extending between the proximal and distal ends and communicating at the distal ends. One of the reasons for this feature is to keep the treating elements within the catheter. For example, one of the lumens (the seed lumen) is used for transferring the treating elements using pressurized fluid from the proximal end of the catheter to the distal end where the treatment is desired. The second lumen is a fluid return lumen for the pressurized fluid to return to the proximal end of the catheter and to return the treating elements to the proximal end of the catheter and back into the transfer device. In order to effect a transfer of the treating elements from the seed lumen to the fluid return lumen, the two lumens must be in communication at the distal end of the catheter. If the two lumens are not in communication at the distal end, the treating elements could not be transferred from the seed lumen to the fluid return lumen after treatment had been effected. In addition, the lumens should be closed at the distal end so that the treating elements are not released into the body but can be returned by the fluid return lumen. Applicants discovered that by making the fluid return lumen with an elliptical shape, the area for fluid flow was increased without compromising the outer diameter of the catheter. See e.g. page 35 of the present application.¹

¹ Applicants have made minor amendments to Claim 21 to remove any possible ambiguity as to the structure of the

In contrast, Jang appears to disclose² a balloon catheter having a common lumen at its distal end. Into this common lumen, the guidewire is advanced as are the working element, such as an ultrasound imaging transducer. Hence, there is only one, and not two lumens at the distal end of the catheter, as required in the claimed invention. As a result, there cannot be an disclosure or suggestion in Jang of two lumens communicating at the distal end. The disclosure in Jang of lumens 25 and 23 opening into common lumen 60 does not occur at the distal end of the catheter, as in independent Claim 21.

Such a feature is also not disclosed or suggested by Bell or Yock. As shown in the figures in both Bell and Yock, none of the lumens communicate with each other at the distal ends.

Hence, even if these references were properly combined (which Applicants do not admit), the combination still fails to disclose or suggest the claimed invention, and independent Claim 21 and dependent Claims 42 and 43 are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Rejection of Claim 22

The Examiner also rejects Claim 22 under 35 USC §103(a) over Jang in view of Yock or Bell and further in view of Fiddian-Green. This rejection is also traversed.

This dependent claim is at least patentable over the cited references for the reasons described above for independent Claim 21.

claimed invention.

² Once again, Applicants are forced to speculate where the Examiner found the claimed features as no cites are provided in the Office Action to where the claimed elements are allegedly shown in Jang. It is respectfully submitted that this fails to provide a prima facie obviousness and that the rejection should be withdrawn for at least this reason.

Further, Fiddian-Green is directed to a remote sensing tonometric catheter which is very different than a catheter for use in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element, as in the claimed invention. Further, the catheter in Figs. 1-2 of Fiddian-Green appears to have a single lumen extending from the proximal end to the distal end of an elongated tube. The lumens of Figs. 4 are explicitly stated as being noncommunicating with each other (see col. 6, lns. 40-44 in Fiddian-Green). The lumens of Figs. 5 are merely connected with a catheter at the end of the lumen, not in communication with another lumen which extends from the proximal end to the distal end of the elongated tube.

Additionally, Fiddian-Green does not disclose or suggest "at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of the patient, said radiopaque marker being located within said first lumen at said distal end and providing a fluid flow path between said first and second lumen," as recited in Claim 22. Instead, Fiddian-Green discloses a radiopaque tungsten plug which is intended to "block" the lumen, or a radiopaque tungsten rod which terminate the end of the lumen. See Col. 7, lns. 20-34 of Fiddian-Green. Hence, the reference does not disclose or suggest a radiopaque marker that provides a fluid path between the first and second lumens.

Therefore, for at least the above-stated reasons, Claim 22 is not disclosed or suggested by the cited references and is patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Rejection of Claims 38-39

The Examiner also rejects Claims 38-39 under 35 USC §103 as being unpatentable over Waksman et al. and further in view of Littmann et al. This rejection is also respectfully traversed.

Claim 38 is directed to a catheter for use in an intraluminal treatment system. The catheter has three lumens, one of which is sized to receive a guidewire. Importantly, as specifically recited in the claim, the distal end of this lumen has a lining that resists damage from the guidewire as the catheter is delivered over the guidewire to the treatment site. This is described for example in the specification on page 36, lines 21-26 and is shown in Fig. 42C. As explained therein, for example, such a lining is of a sufficient durometer to resist the guidewire from damaging the distal end of the lumen. Applicants have amended the claim to make this feature clear.

Applicants can find no disclosure of such a lining in the cited references. The Examiner recites Littmann as showing such a lining. However, Littmann merely discloses a lining formed of a lubricous material (col. 6, lns. 5-12). There is no mention of a material that resists damage from the guidewire nor of its having a higher durometer than the tip of the catheter. Accordingly, the rejection of Claim 38 should be withdrawn.

Claim 39 is dependent from Claim 38 and requires the guidewire lumen lining to comprise a blend of a high density polyethylene and a low density polyethylene. The Examiner acknowledges that Waksman does not disclose this feature and still does not explain where Littman discloses this feature.

Therefore, for at least the above-stated reasons, Claims 38 and 39 are not disclosed or suggested by the cited references and are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.


CONCLUSION

Therefore, for at least the above-stated reasons, the present application is now in an allowable condition and should be allowed.

Please charge our deposit account 50/1039 for any further fee for this amendment.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,



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